

Appl. No. 09/869,060
Amendment dated: November 4, 2006
Reply to OA of: May 4, 2006

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1-23(canceled).

24(currently amended). A method for assaying homocysteine in a sample, said method comprising[:] contacting said sample with ~~two a stable aqueous reagents, said reagents together containing~~ first reagent mixture, said first reagent mixture comprising

a) ~~a polyhaptan having S-adenosine homocysteine (SAH) as hapten moieties thereof~~ comprising S-adenosine homocysteine;

b) ~~a first enzyme, being the homocysteine converting enzyme SAH hydrolase;~~

c) ~~a primary antibody capable of binding to said polyhaptan whereby to produce a complex;~~

d) ~~optionally one or more of:~~

i) ~~adenosine or an adenosine analog,~~

optionally one or more of:

ii) ~~a reducing agent;~~

an agent which promotes precipitation of a complex between the polyhaptan and a primary antibody described below;

iii) ~~a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase; and~~
contacting said sample with a stable aqueous second reagent mixture, said second reagent mixture comprising

a primary antibody capable of binding to said polyhaptan whereby to produce a complex,

a first enzyme, being the homocysteine converting enzyme SAH hydrolase;

optionally one or more of

- iv) a second antibody capable of binding to said complex;
- v) an agent which promotes precipitation of said complex;
a second enzyme capable of converting said adenosine or
adenosine analog or a conversion product of said SAH
hydrolase;

~~wherein said primary antibody is capable of binding to said adenosine or~~
~~adeosine analog or to a conversion product of said first or second enzymes,~~
~~whereby the quantity of said complex produced is indicative of the content of~~
~~homocysteine in said sample;~~

and photometrically detecting said complex[[:]].

~~wherein said reagents consist of a first reagent comprising said polyhaptan,~~
~~optionally said adenosine or adenosine analog, optionally said reducing agent, and~~
~~optionally said agent which promotes precipitation of said complex; and a second~~
~~reagent comprising said primary antibody, said first enzyme, optionally said second~~
~~antibody, and optionally said agent which promotes precipitation of said complex.~~

25(currently amended). A method for assaying homocysteine in a sample,
said method comprising[[:]] contacting said sample with three a stable aqueous
reagents, said reagents together containing first reagent mixture, said first reagent
mixture comprising

- a) a polyhaptan having S-adenosine homocysteine (SAH)as hapten
moieties thereof comprising S-adenosine homocysteine;
- b) ~~a first enzyme, being the homocysteine converting enzyme SAH~~
~~hydrolase;~~
- c) ~~a primary antibody capable of binding to said polyhaptan whereby to~~
~~produce a complex;~~
- d) ~~optionally one or more of:~~
 - i) adenosine or an adenosine analog,

Appl. No. 09/869,060
Amendment dated: November 4, 2006
Reply to OA of: May 4, 2006

optionally one or more of:

ii) a reducing agent;

an agent which promotes precipitation of a complex between the polyhapten and the primary antibody described below;

iii) a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase; and contacting said sample with a stable aqueous second reagent mixture, said

second reagent mixture comprising

a primary antibody capable of binding to said polyhapten whereby to produce a complex,

optionally one or more of

iv) a second antibody capable of binding to said complex;

v) an agent which promotes precipitation of said complex;

a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase;

contacting said sample with a stable aqueous third reagent mixture, said third reagent mixture comprising

a first enzyme, being the homocysteine converting enzyme SAH hydrolase;

optionally one or more of

a second antibody capable of binding to said complex;

an agent which promotes precipitation of said complex;

a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase;

and photometrically detecting said complex.

~~wherein said primary antibody is capable of binding to said adenosine or adenosine analog or to a conversion product of said first or second enzymes, whereby the quantity of said complex produced is indicative of the content of homocysteine in said sample;~~

Appl. No. 09/869,060
Amendment dated: November 4, 2006
Reply to OA of: May 4, 2006

~~and photometrically detecting said complex;
wherein two or three of said reagents optionally contain said agent which
promotes precipitation of said complex, and neither of said primary antibody or said
first enzyme is present in the same reagent as said polyhapten or said optional
adenosine or adenosine analog.~~

26(currently amended). The method as claimed in claim 24 wherein said optional secondary antibody is present in at least one of said ~~reagents~~ reagent mixtures.

27(previously presented). The method as claimed in claim 24 wherein said complex is determined nephelometrically or turbidimetrically.

28(previously presented). The method as claimed in claim 24 wherein photometric determination takes place before complex generation is complete.

29(previously presented). The method as claimed in claim 24 wherein said sample is a serum or plasma sample.

30(currently amended). The method as claimed in claim 24 wherein at least one of said ~~reagents~~ reagent mixtures contains said optional agent which promotes precipitation of said complex.

31(previously presented). The method as claimed in claim 30 wherein said agent which promotes precipitation is polyethylene glycol.

32(currently amended). The method as claimed in claim 24 wherein at least one of said ~~reagents~~ reagent mixtures further comprises a carrier protein.

33(previously presented). The method as claimed in claim 24 wherein said polyhaptten consists of a backbone structure onto which said hapten moieties are bound.

34(previously presented). The method as claimed in claim 33 wherein said backbone structure is porcine thyroglobulin.

35(currently amended). The method as claimed in claim 24 wherein at least one of said ~~reagents~~ reagent mixtures contains said primary and secondary antibodies and additionally contains a chaotropic salt.

36(currently amended). A homocysteine assay reagent kit comprising ~~two a~~ stable aqueous reagents, said reagents together containing first reagent mixture, said first reagent mixture comprising

- a) a polyhaptten having ~~S-adenosine homocysteine (SAH)as~~ hapten moieties ~~thereof~~ comprising S-adenosine homocysteine;
- b) ~~a first enzyme, being the homocysteine converting enzyme SAH hydrolase;~~
- c) ~~a primary antibody capable of binding to said polyhaptten whereby to produce a complex;~~
- d) ~~optionally one or more of:~~
 - i) ~~adenosine or an adenosine analog,~~
optionally one or more of:
 - ii) a reducing agent;
an agent which promotes precipitation of a complex between the polyhaptten and the primary antibody described below;
 - iii) a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of ~~said~~ SAH hydrolase; ~~and~~

Appl. No. 09/869,060
Amendment dated: November 4, 2006
Reply to OA of: May 4, 2006

and a stable aqueous second reagent mixture, said second reagent mixture comprising

a primary antibody capable of binding to said polyhapten whereby to produce a complex,

optionally one or more of

iv) a second antibody capable of binding to said complex;

v) an agent which promotes precipitation of said complex;

a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase.

~~wherein said primary antibody is capable of binding to said adenosine or adenosine analog or to a conversion product of said first or second enzymes, whereby the quantity of said complex produced is indicative of the content of homocysteine in said sample;~~

~~and photometrically detecting said complex;~~

~~wherein said reagents consist of a first reagent comprising said polyhapten, optionally said adenosine or adenosine analog, optionally said reducing agent, and optionally said agent which promotes precipitation of said complex; and a second reagent comprising said primary antibody, said first enzyme, optionally said second antibody, and optionally said agent which promotes precipitation of said complex.~~

37(currently amended). A homocysteine assay reagent kit comprising three a homocysteine assay reagent kit comprising a stable aqueous reagents, said reagents together containing first reagent mixture, said first reagent mixture comprising

a) a polyhapten having ~~S-adenosine homocysteine (SAH)~~as hapten moieties thereof comprising S-adenosine homocysteine;

b) ~~a first enzyme, being the homocysteine converting enzyme SAH hydrolase;~~

c) ~~a primary antibody capable of binding to said polyhapten whereby to produce a complex;~~

d) ~~optionally one or more of:~~

i) ~~adenosine or an adenosine analog,~~

optionally one or more of:

ii) ~~a reducing agent;~~

an agent which promotes precipitation of a complex between the polyhapten and the primary antibody described below;

iii) ~~a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase; and~~

a stable aqueous second reagent mixture, said second reagent mixture comprising

a primary antibody capable of binding to said polyhapten whereby to produce a complex,

optionally one or more of

iv) ~~a second antibody capable of binding to said complex;~~

v) ~~an agent which promotes precipitation of said complex;~~

a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase;

and a stable aqueous third reagent mixture, said third reagent mixture

comprising

a first enzyme, being the homocysteine converting enzyme SAH hydrolase;

optionally one or more of

a second antibody capable of binding to said complex;

an agent which promotes precipitation of said complex;

a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase.

Appl. No. 09/869,060
Amendment dated: November 4, 2006
Reply to OA of: May 4, 2006

~~wherein said primary antibody is capable of binding to said adenosine or adenosine analog or to a conversion product of said first or second enzymes, whereby the quantity of said complex produced is indicative of the content of homocysteine in said sample;~~

~~and photometrically detecting said complex;~~

~~wherein two or three of said reagents optionally contain said agent which promotes precipitation of said complex, and neither of said primary antibody or said first enzyme is present in the same reagent as said polyhapten or said optional adenosine or adenosine analog.~~

38(currently amended). The kit as claimed in claim ~~[[35]]~~36 wherein said optional secondary antibody is present in at least one of said ~~reagents~~ reagent mixtures.

39(currently amended). The kit as claimed in claim ~~[[35]]~~36, wherein at least one of said ~~reagents~~ reagent mixtures contains said agent which promotes precipitation of said complex.

40(currently amended). The kit as claimed in claim ~~[[38]]~~39 wherein said agent which promotes precipitation is polyethylene glycol.

41(currently amended). The kit as claimed in claim ~~[[35]]~~36 wherein at least one of said ~~reagents~~ reagent mixtures further comprises a carrier protein.

42(currently amended). The kit as claimed in claim ~~[[35]]~~36 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

Appl. No. 09/869,060
Amendment dated: November 4, 2006
Reply to OA of: May 4, 2006

43(currently amended). The kit as claimed in claim ~~[[41]]~~42, wherein said backbone structure is porcine thyroglobulin.

44(currently amended). The kit as claimed in claim ~~[[35]]~~36 wherein at least one of said ~~reagents~~ reagent mixtures contains said primary and said secondary antibodies and additionally contains a chaotropic salt.

45(new). The method as claimed in claim 25 wherein said optional secondary antibody is present in at least one of said reagent mixtures.

46(new). The method as claimed in claim 25 wherein said complex is determined nephelometrically or turbidimetrically.

47(new). The method as claimed in claim 25 wherein photometric determinatination takes place before complex generation is complete.

48(new). The method as claimed in claim 25 wherein said sample is a serum or plasma sample.

49(new). The method as claimed in claim 25 wherein at least one of said reagent mixtures contains said optional agent which promotes precipitation of said complex.

50(new). The method as claimed in claim 25 wherein at least one of said reagent mixtures further comprises a carrier protein.

51(new). The method as claimed in claim 25 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

Appl. No. 09/869,060
Amendment dated: November 4, 2006
Reply to OA of: May 4, 2006

52(new). The method as claimed in claim 25 wherein at least one of said reagent mixtures contains said primary and secondary antibodies and additionally contains a chaotropic salt.

53(new). The kit as claimed in claim 37 wherein said optional secondary antibody is present in at least one of said reagent mixtures.

54(new). The kit as claimed in claim 37, wherein at least one of said reagent mixtures contains said agent which promotes precipitation of said complex.

55(new). The kit as claimed in claim 37 wherein at least one of said reagent mixtures further comprises a carrier protein.

56(new). The kit as claimed in claim 37 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

57(new). The kit as claimed in claim 37 wherein at least one of said reagent mixtures contains said primary and said secondary antibodies and additionally contains a chaotropic salt.